EXHIBIT 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **ETHICON WAVES 2 & 3 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DECLARATION OF MARY CARMEL LOWE

Mary Carmel Lowe deposes and says:

1. My name is Mary Carmel Lowe. I am over twenty-one years of age and of sound mind. I am competent to testify about all of the matters set out in this Declaration.

2. I have been employed by Ethicon Sarl since September of 2011, holding the position of Quality Systems Supervisor in Neuchatel, Switzerland. I began working for Johnson & Johnson in 1991 and have worked in a variety of positions including Manufacturing Production Supervisor, Training Supervisor and Manager, and Operations Support with Ortho-Clinical Diagnostics, and Records Management & Change Control positions with Obtech Medical, an Ethicon Endosurgery company.

3. I make this affidavit (i) to describe the contents of a Device History Record ("DHR"), or batch record; (ii) explain the steps involved in compiling a DHR; and (iii) describe

the time and effort spent compiling the DHRs for the particular lots involved in the Wave 1 cases of the MDL litigation.

4. As the Quality Systems Supervisor at Ethicon Sarl for the past four years, I have focused on ensuring compliance with franchise procedures and monitoring NCRs and CAPAs, as well as facilitating the batch review process for the complaint handling unit as related to the litigation. I have become familiar with how batch records are compiled and reviewed, both as part of the complaint review process and in response to litigation requests.

5. The DHR is a collection of manufacturing records as defined by Ethicon and required by the FDA pertaining to the manufacture of a lot of finished goods. A DHR for a particular product lot consists of Lot Travel Record (LTR) that charts the raw material and component lots that comprise a particular finished good lot and charts the lot's manufacturing process. A DHR also includes packaging information, information relating to component/raw material lot records, and product sterilization records.

6. The DHR also contains documentation of any non-conformance reports (NCRs) generated during the manufacture of a particular lot. However, a lot will not be released until any associated NCRs have been resolved. The DHRs contain documentation of the resolution of any NCRs opened with respect to that particular batch.

7. It is my understanding that summary non-conformance reports have been previously collected and produced in the litigation. These documents identify any non-conformance reports opened for a particular lot number. The reports contain a description of the non-conformance, the investigation into the non-conformance, and the correction of the issue, among other information.

8. Ethicon Sarl maintains hard copies of the manufacturing records for the raw materials and components of the TVT family of products. These individual records are manually collected and compiled to create a DHR file in producible form.

9. For each lot number at issue, a trained employee must begin the process of compiling the DHR by reviewing the particular LTR, which provides information for raw material lots, component part lots, and sterilization information that comprise a particular finished good lot. This process varies depending on the particular product line and also the specific raw material and component part requirements for the particular finished good lot.

10. The employee then locates the identified documentation associated with each component of the finished good using the company's record retention documentation. Documentation for products manufactured two or more years ago is stored offsite at the Secur Archive facility in Bern, Switzerland.

11. The employee then coordinates retrieval of each relevant box of records and reviews them onsite to identify the specific documentation associated with a given lot number.

12. The employee compiles information pertaining to each lot, which is then reviewed for completeness.

13. The employee then scans and quality checks the hard copy documents prior to distribution outside of the company.

14. The volume of each DHR and the compilation time required varies depending on the number of unique raw material and component lots used in the manufacture of the particular finished product lot. On average, the DHR for an individual lot consists of 10 separate files, and ranges in volume from 40-50 pages, though some can be upwards of 100 pages. Because

the documentation must be compiled manually by trained employees, our facility can process the compilation and provision of approximately 5-7 DHRs per week.

15. In connection with the 200 cases involved in Wave 1 of the MDL litigation, my department has processed 186 DHRs. This has required us to order and sort through 550 boxes of documentation from offsite storage, and manually review and scan approximately 1,700 individual files that comprise the DHRs. While there were over 200 unique lots identified for the 200 cases, approximately 20 lots had been the subject of prior litigation requests; 28 lots corresponded with records that were destroyed in the Secur Archive fire in Lausanne, Switzerland in 2009; and 29 lots were for Prolene Soft, Prolene, or Gynemesh PS products that are maintained separately by Ethicon's San Lorenzo and San Angelo facilities; and additional lots were misidentified or unidentified.

16. Approximately 2,700 hours of employee time will have been devoted to compiling the batch records & associated documents for use in the Wave 1 cases.

17. Our business unit is not able to absorb such a high level of litigation-related activity. To undertake the collection of batch records for Wave 1, my department sought assistance from four additional employees from another Johnson & Johnson entity who are only available for a limited period of time. If we were required to produce such a vast amount of DHRs in the future, I would likely have to recruit and train additional employees to assist in any further litigation-related requests of this nature, a process which could take a minimum of three weeks and would divert additional resources away from the site's routine business of manufacturing Ethicon medical devices.

18. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 24th day of November, 2015.

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MARY CARMEL LOWE